

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 21-26 are requested to be cancelled.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. No new matter is being added.

After amending the claims as set forth above, claims 18-20 are now pending.

I. Claim Rejections – 35 U.S.C. § 112, first paragraph

Claims 18 and 20-26 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement. Specifically, the examiner concedes that claims directed to “rat GLP-2 and homologous GLP-2 for other vertebrate mammals” are enabled. Office action at 2. However, the examiner contends that the claims are not enabled for “GLP-2 from non-vertebrate GLP-2 animals.” *Id.* Applicant respectfully traverses this ground of rejection.

As claimed below, the specification provides sufficient guidance to allow one of skill in the art to practice the claimed invention without undue experimentation.

The claims recite the administration of different GLP-2 peptides. Specifically, claim 18 recites “GLP-2,” and claims 19 and 20 recite specific sequences defined structurally. The specification contains a number of examples of GLP-2 from different species of animals, and the specification also contains extensive description of how GLP-2 analogs can be made. *See e.g.*,

page 7, line 27 – page 15, line 13. Indeed, the specification discusses the structural features of GLP-2 and how analogs can be made while preserving biological activity. *Id.*; example 1.

The examiner argues that the specification provides insufficient guidance for non-vertebrate GLP-2. However, there is no evidence that GLP-2 is any different than vertebrate GLP-2. Indeed, Applicant is not aware of any non-vertebrate GLP-2 sequences. Accordingly, one of skill in the art would be able to use select GLP-2 peptides based on the structural and functional guidance provided in the specification.

The examiner also argues that screening peptides for activity would constitute undue experimentation, because “[t]housands of compounds might be unsuccessfully screened for such a compound....” Office action at 2. However, even extensive experimentation is not undue when the experimentation is merely routine. MPEP § 2164.06. Indeed, screening for biological activity is not undue, particularly when the specification contains extensive guidance as to the structural characteristics of the peptide. See *Ex parte Mark*, 12 USPQ2d 1904 (BPAI 1989). Accordingly, merely screening GLP-2 peptides for activity is not undue.

For at least these reasons, one of skill in the art could practice the claimed invention without undue experimentation. Accordingly, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

II. Claim Rejection 35 U.S.C. § 102

Claims 21-26 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 5,432,156 to Matsuno *et al.* According to the examiner, Matsuno discloses an analog of GLP-2, glicentin. The examiner contends that this analog anticipates the claims.

While not acquiescing in the propriety of the rejection, Applicant has cancelled claims 21-26. Accordingly, the rejection is rendered moot.

III. Claim Rejections – *Schneller* Double Patenting

Claims 18-26 stand rejected “under the judicially created doctrine of double patenting over claims 2, 4, 11, 17, 25, 39, 57, 63, 66-68, 48, and 50 of U.S. Patent No. 5,990,077.” According to the examiner, the claims are not “patentably distinct from each other because the difference between the two invention [*sic*] is the scope of the GLP-2 analogs and are directed to methods of treating the small intestine, which would necessarily increase nutritional uptake.” Office action at 8. The examiner further notes that there is no apparent reason why the present claims were not presented earlier and cites *In re Schneller*, 397 F.2d 350 (CCPA 1968) as support. Applicant respectfully traverses this ground of rejection.

Applicant understands that this rejection is based on *In re Schneller*, 397 F.2d 350 (CCPA 1968) (“*Schneller*”). See MPEP § 804(II)(B)(2); Form ¶ 8.38. Rejections “based on *Schneller* **will be rare**.” *Id.* (emphasis original). Indeed, *Schneller* has been limited to its particular facts and is not a rule of general applicability. See *e.g.*, *id.*; *Ex parte Davis*, Appl. No. 08/486,545 at 10-11 (BPAI March 22, 2000). As discussed below, the present case is not one of the “rare” cases where a *Schneller* rejection is appropriate.

A. **The Facts Of The Present Case Are Distinct From *Schneller***

In *Schneller*, the patent applicant’s invention was an improvement on an old clip of combination ABC. The applicant discovered that the clip could be improved by adding X, Y, or preferably both. Accordingly, the applicant filed an application disclosing the improvement and received a patent for a clip comprising BCX and ABCX. Later on, the applicant tried to obtain claims to a clip comprising ABCY and ABCXY. These claims triggered the double patenting rejection.

The present case is different. As noted by the examiner, the GLP-2 peptides recited in the claims of the present application differ from those recited in the claims of the ‘077 patent. These different peptides were not disclosed in the application leading to the ‘077 patent. On the other

hand, the claimed subject matter at issue in *Schneller* was disclosed in the earlier application. *See* MPEP § 804(II)(B)(2) (noting importance of disclosure in original application).

In addition, the present claims are directed to methods for “improving the function of gastrointestinal tissue” rather than methods for “promoting the growth of small intestine tissue,” as in the ‘077 patent. Thus, the claims are not directed to the same subject matter. On the other hand, the claims in *Schneller* were both directed to a “clip.” Thus, the present case presents a different scenario than *Schneller*.

B. The “Right to Exclude” Will Not Be Improperly Extended

The claims of the present application differ from the past application, as noted above. For example, the claims recite different GLP-2 peptides and are directed to different methods. The determination of whether claims improperly extend the “right to exclude” is not whether or not one set of claims dominates another. MPEP § 804(II)(B)(2). When the present claims are directed to different methods employing different peptides, the right to exclude is not being improperly extended.

The examiner notes that there is no apparent reason why the present claims were not presented earlier. However, the present application is a continuation of 08/632,533, which is a continuation-in-part of 08/422,540, which issued as the ‘077 patent. In other words, the present application contains subject matter not disclosed in the application leading to the ‘077 patent. Thus, Applicant could not have presented the current claims at the time the ‘077 patent issued.

C. The *Schneller* Rejection is Procedurally Improper

The *Schneller* rejection should be withdrawn, because the appropriate procedures were not followed in making the rejection. Specifically, the “Technology Center (TC) Director must approve any nonstatutory double patenting rejections based on *Schneller*.” MPEP § 804(II)(B)(2) (emphasis added). In this case, there is no evidence that the rejection was

approved by the TC Director. See *Ex Parte Kageyama*, 2003 WL 22282273, Appl. No. 09/411,370 (BPAI June 5, 2003) (remanding case to examiner for consideration of MPEP guidelines, including TC Director approval). Accordingly, the rejection is improper and should be withdrawn.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of this ground of rejection.

CONCLUSION

Applicant believes that the present application is now in condition for allowance.
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a
telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be
required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to
Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check
being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even
entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit
Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers
submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and
authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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